



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,179	06/20/2000	Maura Rooney	BSP2102US02	5883
22852	7590	03/06/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	09/597,179	ROONEY ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25,28-30,32-39,57,58 and 60-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25,28-30,32-39,57,58 and 60-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 22, 25, 30, 32, 38, 57, 58, 62, 68, 89, 90 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,171,383 to Sagaye et al.

In regards to claims 22, 25, 30, 32, 38, 57, 58, 62, 68, 89, 90 and 93, Sagaye et al. discloses a guide wire (Figure 3) including an elongate core (1) composed of a nickel-titanium alloy (Col. 3, lines 27 – 29), a proximal end and a tapered distal end; a continuous unitary coil having a circular cross-section and being composed of a second material (Col. 2, lines 40 – 42) that surrounds a portion of the length of the core and extends beyond the distal end of the core by a plurality of turns of the coil (Figure 3); and a polymeric tip contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material that extends within spaces between adjacent turns of the coil (Col. 2, lines 59 – 63). Sagaye et al. discloses the coil surrounding the entire length of the core (Col. 4, lines 61 – 64; Figure 3). Sagaye et al. discloses the tip including radio-opaque material (Col. 4, lines 17 – 24). Sagaye et al. discloses a length of the core having a constant diameter (Figure 3).

Art Unit: 3736

3. Claims 22, 30, 34, 35, 38, 57, 64, 65, 68, 89 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,833,631 to Nguyen.

In regards to claims 22, 30, 34, 35, 38, 57, 64, 65, 68, 89 and 90, Nguyen discloses a guide wire including an elongate core (102) composed of a nickel-titanium alloy (Col. 5, lines 6 – 8), a proximal end and a tapered distal end; a continuous unitary coil (204) having a circular cross-section and being composed of a second material (Col. 3, lines 56 – 67; Col. 4, lines 45 – 48) that surrounds a portion of the length of the core and extends beyond the distal end of the core (Col. 4, lines 36 – 44) by a plurality of turns of the coil; and a polymeric tip (206) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material (Col. 4, lines 6 – 16) that extends at least partially in spaces between adjacent turns of the coil when shrunk. Nguyen discloses a length of the core having a constant diameter. Nguyen discloses the coil comprising a lubricious coating (Col. 4, lines 6 – 7).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 22, 25, 28, 30, 34, 35, 37, 38, 57, 58, 60, 63 – 65, 67, 68, 89, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice.

In regards to claims 22, 25, 28, 30, 34, 35, 37, 38, 57, 58, 60, 63 – 65, 67, 68, 89, 90 and 91, Roubin et al. discloses a guide wire (Figure 1) including an elongate core (21) having a proximal

Art Unit: 3736

portion and a tapered distal portion (22); a continuous unitary stainless steel coil (Col. 3, lines 20 – 24) having a circular cross-section and that surrounds a substantial portion of the length of the core and extending distal of the core by a plurality of turns (Figure 2); and a tip (24) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Col. 3, lines 36 – 39). Roubin et al. discloses the tip being a weld joint, but fails to disclose the tip comprising a polymeric material. Roubin et al. also fails to disclose the core comprising a nickel-titanium alloy. Additionally, Roubin et al. fails to disclose the coil surrounding the entire length of the core, having a rectangular cross-section or having a lubricious coating. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). Stice also discloses the coil being located only at the tip or extending the entire length of the core (Col. 2, lines 49 – 51), having a rectangular cross-section (Col. 2, lines 44 – 49) and having a lubricous coating thereon (Col. 4, lines 6 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Roubin et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Roubin et al. to include a lubricous coating thereon as taught by Stice (Col. 4, lines 6 – 10) in order to allow the guidewire to more easily travel through the patient's vasculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Roubin et al. to include a rectangular cross-section as taught by Stice in that Stice discloses circular and rectangular cross-

Art Unit: 3736

sections as being functionally equivalent (Col. 2, lines 44 – 49) and therefor interchangeable.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Roubin et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable.

6. Claims 29, 61 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claims 29, 61 and 92, Roubin et al. discloses a guide wire (Figure 1) including an elongate core (21) having a proximal portion and a distal portion (22) and a constant diameter along a length (Col. 3, line 31); a continuous unitary stainless steel coil (Col. 3, lines 20 – 24) having a circular cross-section and that surrounds a substantial portion of the length of the core and extending distal of the core by a plurality of turns (Figure 2); and a tip (24) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Col. 3, lines 36 – 39). Roubin et al. discloses the tip being a weld joint, but fails to disclose the tip comprising a polymeric material. Roubin et al. also fails to disclose the core comprising a nickel-titanium alloy. Additionally, Roubin et al. fails to disclose the coil being composed of a precipitation hardenable alloy. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Roubin et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved

Art Unit: 3736

body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Roubin et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable. Beisel discloses a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Roubin et al. in view of Stice to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

7. Claims 32 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 5,885,227 to Finlayson.

In regards to claims 32 and 62, Roubin et al. discloses a guide wire (Figure 1) including an elongate core (21) having a proximal portion and a tapered distal portion (22); a continuous unitary stainless steel coil (Col. 3, lines 20 – 24) having a circular cross-section and that surrounds a substantial portion of the length of the core and extending distal of the core by a plurality of turns (Figure 2); and a tip (24) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Col. 3, lines 36 – 39). Roubin et al. discloses the tip being a weld joint, but fails to disclose the tip comprising a polymeric material including a radio-opaque material. Roubin et al. also fails to disclose the core comprising a nickel-titanium alloy. However, Stice discloses a guidewire having a

Art Unit: 3736

nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Roubin et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Roubin et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable. Finlayson discloses a guide wire having a polymeric tip (20) that includes radio-opaque material (Col. 3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Roubin et al. in view of Stice to include radio-opaque material as taught by Finlayson to allow the tip of the guide wire to be seen with an imaging device while performing a medical procedure.

8. Claims 36 and 66, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claims 34 and 64 above, and further in view of U.S. Patent No. 5,997,517 to Whitbourne.

9. In regards to claims 36 and 66, Roubin et al. in view of Stice discloses a polymeric coating, but fail to disclose the coating being colored. Whitbourne teaches the use of a colored coating with various medical devices such as guide wires to enhance the performance of the devices (Col. 4, lines 2 – 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guide wire as disclosed by Roubin et al. in view of Stice to include a colored

Art Unit: 3736

coating as taught by Whitbourne to enhance the performance of the guide wire by assisting in the identification.

10. Claims 39 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claims 22 and 57 above, and further in view of U.S. Patent No. 5,174,302 to Palmer.

In regards to claims 39 and 69, Roubin et al. in view of Stice disclose a unitary coil but fail to disclose the unitary coil comprising a multifilar wire. However, Palmer discloses a unitary coil comprising a multifilar wire (Col. 4, lines 17 – 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Roubin et al. in view of Stice to include a multifilar wire coil as taught by Palmer in order to create intermittent bands or regions of high radiopaqueness (Col. 4, lines 25 – 26) to aid in the visualization of the guidewire during a medical procedure.

11. Claims 84, 85, 87, 88 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 4,932,419 to de Toledo.

In regards to claims 84, 85, 87, 88 and 95, discloses a guide wire (Figure 1) including an elongate core (21) having a proximal portion and a tapered distal portion (22); a continuous unitary stainless steel coil (Col. 3, lines 20 – 24) having a circular cross-section and that surrounds a substantial portion of the length of the core and extending distal of the core by a plurality of turns (Figure 2); and a tip (24) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Col. 3, lines 36 – 39). Roubin et al. discloses the tip being a weld joint, but fails to disclose the tip comprising a polymeric material. Roubin et al. also fails to disclose the core comprising a nickel-

Art Unit: 3736

titanium alloy. Additionally, Roubin et al. fails to disclose the coil surrounding the entire length of the core, having a rectangular cross-section or having a lubricious coating. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). Stice also discloses the coil being located only at the tip or extending the entire length of the core (Col. 2, lines 49 – 51), having a rectangular cross-section (Col. 2, lines 44 – 49) and having a lubricious coating thereon (Col. 4, lines 6 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Roubin et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Roubin et al. to include a lubricious coating thereon as taught by Stice (Col. 4, lines 6 – 10) in order to allow the guidewire to more easily travel through the patient's vasculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Roubin et al. to include a rectangular cross-section as taught by Stice in that Stice discloses circular and rectangular cross-sections as being functionally equivalent (Col. 2, lines 44 – 49) and therefore interchangeable. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Roubin et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable. De Toledo discloses a guidewire having a multifilar cross-wound coil (Col. 3, lines 3 – 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil

Art Unit: 3736

as disclosed by Roubin et al. in view of Stice to be a multifilar cross-wound coil as taught by de Toledo to improve the torque response and steerability of the guidewire (Col. 3, lines 13 – 18).

12. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,354,257 to Roubin et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 4,932,419 to de Toledo as applied to claim 84 above, and further in view of U.S. Patent No. 5,885,227 to Finlayson.

In regards to claim 86, Roubin et al. in view of Stice and further in view of de Toledo discloses a polymeric tip, but fails to disclose the tip including radio-opaque material. Finlayson discloses a guide wire having a polymeric tip (20) that includes radio-opaque material (Col. 3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Roubin et al. in view of Stice and further in view of de Toledo to include radio-opaque material as taught by Finlayson to allow the tip of the guide wire to be seen with an imaging device while performing a medical procedure.

13. Claims 33, 70 – 74, 76, 77 - 79, 82 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,171,383 to Sagaye et al. in view of U.S. Patent No. 6,139,540 to Rost et al.

In regards to claims 33, 70 – 74, 76, 77 - 79, 82 and 94, Sagaye et al. discloses a guide wire (Figure 3) including an elongate core (1) composed of a nickel-titanium alloy (Col. 3, lines 27 – 29), a proximal end and a tapered distal end; a continuous unitary coil having a circular cross-section and being composed of a second material (Col. 2, lines 40 – 42) that surrounds a portion of the length of the core and extends beyond the distal end of the core (Figure 3); and a polymeric tip contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material that extends within spaces between adjacent turns of the coil (Col. 2, lines 59 – 63). Sagaye

Art Unit: 3736

et al. discloses the coil surrounding the entire length of the core (Col. 4, lines 61 – 64; Figure 3).

Sagaye et al. discloses the tip including radio-opaque material (Col. 4, lines 17 – 24). However, Sagaye et al. fails to disclose the coil having a first coil portion having a first pitch and a second coil portion having a second pitch greater than the first pitch, wherein the second coil portion surrounds the distal end of the core. Additionally, Sagaye et al. fails to disclose the coil comprising a lubricious coating. Rost et al. discloses a guide wire (Figure 3) having a core (32), a stainless steel coil having a first coil portion (35) having a first pitch and a second coil portion (37) having a second pitch greater than the first pitch, wherein the second coil portion surrounds the distal end (46) of the core. Rost et al. discloses the coil comprising a lubricious coating (Col. 9, lines 18 – 24). It would have been obvious to one having ordinary skill in the art to modify the coil as disclosed by Sagaye et al. to include a lubricious coating as disclosed by Rost et al. in order to allow the guide wire to pass easily within a patient's body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Sagaye et al. to include a first coil portion having a first pitch and a second coil portion having a second pitch greater than the first pitch, wherein the second coil portion surrounds the distal end of the core as taught by Rost et al. in order to create a distal section having increased flexibility.

14. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,171,383 to Sagaye et al. in view of U.S. Patent No. 6,139,540 to Rost et al. as applied to claim 70 above, and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claim 75, Sagaye et al. in view of Rost et al. fails to disclose using a precipitation hardened alloy as the coil material. Beisel discloses a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Sagaye et al. in view

Art Unit: 3736

of Rost et al. to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

15. Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 55,171,383 to Sagaye et al. in view of U.S. Patent No. 6,139,540 to Rost et al. as applied to claim 78 above, and further in view of U.S. Patent No. 5,997,517 to Whitbourne.

In regards to claim 80, Sagaye et al. in view of Rost et al. discloses a polymeric coating, but fail to disclose the coating being colored. Whitbourne teaches the use of a colored coating with various medical devices such as guide wires to enhance the performance of the devices (Col. 4, lines 2 – 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guide wire as disclosed by Sagaye et al. in view of Rost et al. to include a colored coating as taught by Whitbourne to enhance the performance of the guide wire by assisting in the identification.

16. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 55,171,383 to Sagaye et al. in view of U.S. Patent No. 6,139,540 to Rost et al. as applied to claim 78 above, and further in view of U.S. Patent No. 4,984,581 to Stice.

In regards to claim 81, Sagaye et al. in view of Rost et al. disclose the coil comprising a circular cross-section, but fails to disclose the coil having a rectangular cross-section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sagaye et al. in view of Rost et al. to include a rectangular cross-section as taught by Stice in that Stice discloses circular and rectangular cross-sections as being functionally equivalent (Col. 2, lines 44 – 49) and therefor interchangeable.

Art Unit: 3736

17. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,171,383 to Sagaye et al. in view of U.S. Patent No. 6,139,540 to Rost et al. as applied to claims 70 above, and further in view of U.S. Patent No. 5,174,302 to Palmer.

In regards to claim 83, Sagaye et al. in view of Rost et al. disclose a unitary coil but fail to disclose the unitary coil comprising a multifilar wire. However, Palmer discloses a unitary coil comprising a multifilar wire (Col. 4, lines 17 – 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sagaye et al. in view of Rost et al. to include a multifilar wire coil as taught by Palmer in order to create intermittent bands or regions of high radiopaqueness (Col. 4, lines 25 – 26) to aid in the visualization of the guidewire during a medical procedure.

18. Claims 22, 25, 28, 37,38, 39, 57, 58, 60, 67, 68, 84, 85, 88, 89, 90, 91 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,154,705 to Fleischhacker et al. in view of U.S. Patent No. 4,984,581 to Stice.

In regards to claims 22, 25, 28, 37,38, 39, 57, 58, 60, 67, 68, 84, 85, 88, 89, 90, 91 and 95, Fleischhacker et al. discloses a guide wire (Figure 7) including an elongate core (53) having a proximal portion and a tapered distal portion (22); a continuous stainless steel (Col. 24, line 30) unitary coil (M, N) having a circular cross-section (Col. 24, lines 23 – 24) and that surrounds a substantial portion of the length of the core and extending distal of the core by a plurality of turns (Figure 7); and a tip (51, 52) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Figure 7). Fleischhacker et al. discloses the coil surrounding the entire length of the core and being a cross-wound multifilar coil (Col. 5, lines 10 – 27). Fleischhacker et al. discloses the coil including a rectangular cross-section (Col. 24, lines 23 – 24). Fleischhacker et al. discloses the tip being a weld

Art Unit: 3736

or solder joint, but fails to disclose the tip comprising a polymeric material. Fleischhacker et al. also fails to disclose the core comprising a nickel-titanium alloy. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Fleischhacker et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Fleischhacker et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable.

Response to Arguments

19. Applicant's arguments filed 11/14/02 have been fully considered but they are not persuasive. Applicant asserts that the polymeric material as disclosed by Nguyen does not extend between adjacent turns of the coil. However, the Examiner disagrees. When the polymeric sleeve is shrunk with heat, a portion of the sleeve inherently protrudes into spaces between adjacent turns of the coil. The claim does not state that the polymeric sleeve touches the core, merely that the tip connects to the core by a polymeric material that extends within spaces between adjacent turns of the coil. In this regards, the polymeric tip (206) is connected to the core (Col. 4, lines 14 – 16) by the polymeric sleeve (112). It is inherent that when shrunk, a portion of the polymeric sleeve at least partially extends within spaces between adjacent turns of the coil. Although, not illustrated in the drawings, this is an inherent property associated with heat shrinkable material. When a heat

Art Unit: 3736

shrinkable tube is positioned over a coil and heated, the material will protrude at least partially within spaces between adjacent turns of the coil (See U.S. Patent No. 5,118,907 to Stout et al., U.S. Patent No. 5,143,122 to Adkins and U.S. Patent No. 5,871,528 to Camps et al.).

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,415,178 to His et al. and U.S. Patent No. 5,531,781 to Alferness et al.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

Mark H. Dering
MARK H. DERING
REGISTERED PATENT EXAMINER
UNITED STATES PATENT & TRADEMARK OFFICE